

# United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO.              | FILING DATE        | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO |
|------------------------------|--------------------|----------------------|------------------------|-----------------|
| 10/038,468                   | 01/03/2002         | Christoph Hehrlein   | 2869                   | 8101            |
| 26822 75                     | 90 10/12/2006      |                      | EXAMINER               |                 |
| WALTER A. HACKLER            |                    |                      | THANH, LOAN H          |                 |
| 2372 S.E. BRIS<br>NEWPORT BE | ACH, CA 92660-0755 |                      |                        | PAPER NUMBER    |
|                              | ,                  |                      | 3763                   |                 |
|                              |                    |                      | DATE MAILED: 10/12/200 | 6               |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |  | $\mathcal{M}$   |              |
|---|--|---|--------------|
|   | Application No.  | Applicant(s)  |              |
|   | 10/038,468   | HEHRLEIN ET AL.   |              |
| Office Action Summary   | Examiner   | Art Unit  | <del>-</del> |
|   | LoAn H. Thanh  | 3763  |              |
| The MAILING DATE of this communication  | appears on the cover sheet   | with the correspondence address -   | 14           |
| Period for Reply  |  |   |              |
| A SHORTENED STATUTORY PERIOD FOR REI WHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory per  - Failure to reply within the set or extended period for reply will, by sta Any reply received by the Office later than three months after the may earned patent term adjustment. See 37 CFR 1.704(b).  | B DATE OF THIS COMMUN<br>R 1.136(a). In no event, however, may a<br>riod will apply and will expire SIX (6) MO<br>atute, cause the application to become | IICATION.  a reply be timely filed  ONTHS from the mailing date of this communica  ABANDONED (35 U.S.C. § 133). |              |
| Status  |  |   |              |
| 1) Responsive to communication(s) filed on 22 2a) This action is FINAL. 2b) T  3) Since this application is in condition for allow closed in accordance with the practice under the condition of | his action is non-final. wance except for formal ma  |   | s is         |
| Disposition of Claims   |  |   |              |
| 4) Claim(s) 29-34 is/are pending in the application 4a) Of the above claim(s) is/are without 5) Claim(s) is/are allowed.  6) Claim(s) 29-34 is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and   | drawn from consideration.  |   |              |
| Application Papers  |  |   |              |
| 9) ☐ The specification is objected to by the Exam 10) ☑ The drawing(s) filed on 03 January 2002 is/a Applicant may not request that any objection to a Replacement drawing sheet(s) including the cor 11) ☐ The oath or declaration is objected to by the   | are: a) $\boxtimes$ accepted or b) $\square$ the drawing(s) be held in abey rection is required if the drawir  | ance. See 37 CFR 1.85(a).  g(s) is objected to. See 37 CFR 1.12   |              |
| Priority under 35 U.S.C. § 119  |  |   |              |
| 12) Acknowledgment is made of a claim for fore a) All b) Some * c) None of:  1. Certified copies of the priority docum 2. Certified copies of the priority docum 3. Copies of the certified copies of the papplication from the International Bur * See the attached detailed Office action for a   | ents have been received. ents have been received in priority documents have been reau (PCT Rule 17.2(a)).  | Application No en received in this National Stage   |              |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB. Paper No(s)/Mail Date  | Paper N  | v Summary (PTO-413)<br>o(s)/Mail Date<br>f Informal Patent Application (PTO-152)                                |              |

Application/Control Number: 10/038,468

Art Unit: 3763

#### **DETAILED ACTION**

#### Election/Restrictions

The Examiner is allowing the shift to species of figure 3 as requested and pointed out by Applicant in his response of 05/22/06.

### Response to Amendment

The specification objection, drawing objection and claim objections have been withdrawn in viewof applicant's amendment and response filed 05/22/06.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29-30,33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Grady (USPN 5,084,011).

Grady teaches a method comprising the steps of oxygenation the blood or tissue with a catheter which includes an oxygenated fluorocarbon solution and changing the temperature of the solution to a temperature between about 0 and 4 degrees Celsius by the refrigeration unit 60 and exposing the device to that fluid. The substrate is considered to be the catheter, syringe or cannula. The means for modulating can be interpreted as the lumen wall of the catheter or the refrigeration unit. The means for exposing is considered to be the lumen wall of the tubular element.

Application/Control Number: 10/038,468

Art Unit: 3763

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowe ( US 6,146,358) in view of Paradis ( US 5,334,142).

Rowe teaches a balloon having a substrate/ controlled release carrier on the surface which incorporates a therapeutic agent to be delivered to the internal tissue of the patient. The means for modulating and exposing is considered to be the inflation lumen of the catheter or the wall or the reservoir. As best understood by the examiner the means of Rowe is able to perform the function of the means that applicant has claimed. (i.e. The structure allows the fluid to come into contact with the substrate/ coating/wall which is considered to be equivalent structure to the balloon catheter of applicant. It is well know that the temperature at which to deliver into a patient would be one of the body's temperatures which are between 0 and 50 degrees Celsius.

Rowe discloses several therapeutic agents, however Rowe is silent to the therapeutic agent to be an elutable oxygenated fluorocarbon solution. Paradis discloses delivery of oxygen carrying fluid (fluorocarbon) for infusion. Paradis further disclose that any agent that is demonstrated as effective when administered

Application/Control Number: 10/038,468

Art Unit: 3763

intravenously may be more effective when administered to the heart by the balloon catheter. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the therapeutic agent of Rowe with the oxygenated fluorocarbon solution as disclosed by Paradis as a substitution of different therapeutic agents for treatment with a balloon catheter.

### Response to Arguments

Applicant's arguments with respect to claims 1-16,19 -28 have been considered but are not persuasive. Both Grady and Paradis discloses teachings of oxygenated fluorocarbon solutions. The rejection is being maintained.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 3763

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LoAn H. Thanh Primary Examiner Art Unit 3763